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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/207, 188 12/08/98 TAI

J 2016-4005US1

HM12/1208

EXAMINER

MORGAN & FINNEGAN  
345 PARK AVENUE  
NEW YORK NY 10154

DEVI. S	ART UNIT	PAPER NUMBER
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1641  
DATE MAILED:

12/08/99

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. 09/207,188	Applicant(s) Blake et al.
Examiner S. Devi, Ph.D.	Group Art Unit 1641



Responsive to communication(s) filed on Dec 8, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 61-79 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 61-79 are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**Election/Restriction**

- 1) Claims 61-79 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 61-72, drawn to a method of immunizing a mammal against group A streptococcal infection by administering a polysaccharide of formula I covalently linked to a protein, classified in class 424, subclass 244.1.
  - II. Claims 73 and 74, drawn to an immune composition comprising opsonic antibodies that bind to a streptococcal polysaccharide of formula I, classified in class 530, subclass 387.5.
  - III. Claims 75-79, drawn to a method of conferring passive immunity by administering a composition comprising opsonic antibodies that bind to a streptococcal polysaccharide of formula I, classified in class 424, subclass 137.1.
- 4) Inventions I, II and III are distinct from one another. Invention II is directed to a product, whereas inventions I and III are drawn to two different methods. The methods of inventions I and III differ from each other in method steps, parameters and compositions used, and ultimate goals accomplished. The method of invention I accomplishes active immunization using a polysaccharide-protein conjugate, whereas the method of invention III accomplishes passive immunization using an antibody composition. The compositions used in the two methods are structurally, functionally, biologically and/or immunogenically distinct from one another.
- 5) Inventions II and III are related as product and process of use. The inventions can be

shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the method of conferring passive immunity against group A streptococcal bacteria can be practiced with another product that is materially different from the composition comprising opsonic antibodies that bind to a streptococcal polysaccharide of formula I, for example, with non-polysaccharide-specific, i.e., protein immunogen-specific opsonic antibodies. The antibody composition of invention I can be used in a materially different process of using the product, for example, in the immunopurification of the group A streptococcal polysaccharide of formula I, or in the generation of anti-idiotypic antibodies.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

6) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

7) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 1999

  
JAMES C. HOUSEL 12/6/99  
SUPERVISORY PATENT EXAMINER



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Dr. S. Devi

ART UNIT: 1641

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY  
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: \_\_\_\_\_  
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